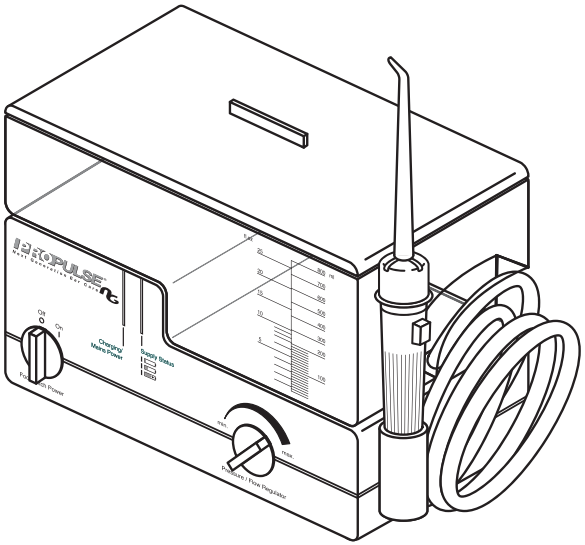


PROPULSE® NG

Next Generation Ear Care

QrX™ Technology

User Manual

English Language Version

CE
0499

MIRAGE HEALTH GROUP

Innovative vision, solutions for life™

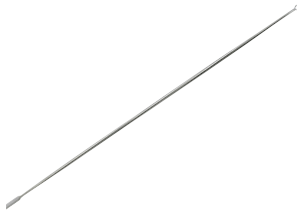
Professional Ear Care with Integrity.

PROPULSE Instruments

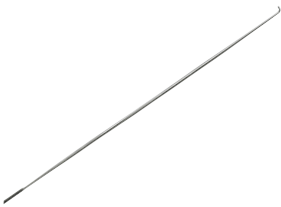
Professional Ear Care with Integrity

Propulse Henckel Style Forceps 3″ (7.6cm)
INS0023

Propulse Jobson Horne Style Probe (1.1mm)
INS0025



Propulse Wax Hook
INS0026



Propulse Hartmann Style Crocodile Forceps
INS0027

Propulse Noots Ear Tank
INS0021

Propulse R/R Dressing Scissors
INS0024

Propulse Tilley Style Aural Dressing Forceps
INS0022

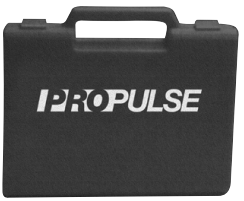
PROPULSE Accessories

Professional Ear Care with Integrity

Propulse Cleaning Tablets (x200 per pack) CL0001

Propulse QrX Single Use Tip (x100 per pack) KIT4002

Propulse Carry Case KIT1005



Propulse Headlamp INS0014

Propulse Replacement Mushroom Valves & Washers - KIT1006

Replacement Reservoir & Lid KIT4004

INTENDED PURPOSE

The Propulse NG Electronic Ear Irrigation System is intended to:

a) Facilitate the removal of cerumen and foreign bodies that are not hygroscopic from the auditory meatus.
b) Remove discharge, keratin or debris from the external auditory meatus by irrigation with warm water.

Reasons for using this procedure are to:

a) Correctly treat otitis externa where the meatus is obscured by debris.
b) Improve conduction of sound into the ear, where impacted wax is believed to be the cause of a hearing defect.
c) Examine the external auditory meatus and the tympanic membrane.
d) Remove a cause of discomfort.

This procedure should ONLY be carried out by a suitably trained clinician.

WARNINGS AND CAUTIONS

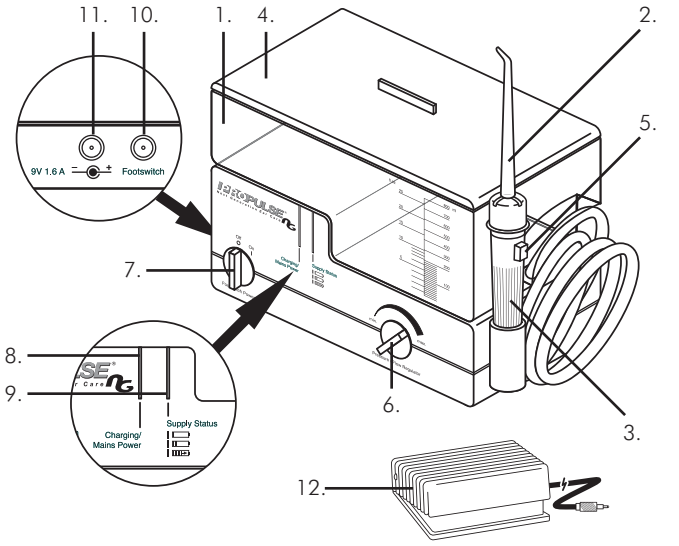
- This manual must be read and understood before the Propulse NG Electronic Ear Irrigation System is used.
- Only suitably trained staff should use the device. Mirage can advise on the availability of training courses offered by relevant organisations.
- The Propulse QrX Tip is "Single Use" and should be disposed of in accordance with local authority guidelines after use.
- The Propulse NG Electronic Ear Irrigation System must not be immersed in water.
- Only clean the device as specified in this manual (See page 10).
- If any changes in performance occur, turn off the Propulse NG Electronic Ear Irrigation System, disconnect from the mains electricity supply and DO NOT use (See page 11).
- The device has no user serviceable parts (See page 11).
- Use recommended Propulse accessories only.
- Do not use Propulse accessories with other devices.
- If the device is to be used for domestic visits, it is strongly recommended that a Propulse Carry Case is used to prevent damage and contamination.
- The Propulse NG Electronic Ear Irrigation System is not user repairable and should be returned to your Propulse supplier or the Mirage Health Group Certified Service Centre (UK customers only) for service and/or repair. It is recommended that the Propulse NG Electronic Ear Irrigation System is serviced annually.

Please note: *Damage caused to your Propulse NG Electronic Ear Irrigation System by the use of accessories, consumables or service agents not recommended by Mirage Health Group, will invalidate your warranty.*

● **DO NOT IRRIGATE** the ears if:

a) Consent is not given and/or the patient is uncooperative.
b) Previous complications occurred following this procedure.
c) There is a history of a middle ear infection in the last six weeks.
d) The patient has undergone ear surgery (apart from grommets that have extruded at least 18 months previously and the patient has been discharged from the ENT dept).
e) The patient has a perforation or there is a history of a mucous discharge in the last year.
f) The patient has a cleft palate (repaired or not).
g) In the presence of acute otitis externa; an oedematous ear canal combined with pain and tenderness of the pinna.
h) If patient complains of pain - **STOP IMMEDIATELY**.

DESCRIPTION



1. Water Container/Reservoir *(Marked for indication only)*
2. Propulse QrX Tip (Single Use)
3. QrX Handle
4. Lid
5. Water Jet 'Stop Button'
6. Pressure/Flow Control Knob
7. Footswitch Power Switch
8. Charging/Mains Power Light
9. Power Status Light
10. Footswitch Socket
11. Power Adaptor Socket
12. Footswitch

The Propulse NG Electronic Ear Irrigation System consists of:

a) The main unit with integral battery and the following user controls:

- A footswitch power switch (7) - this switch powers the equipment on (I) and off (O) in conjunction with the footswitch. (See 'd' below).
- A water pressure/flow control knob (6)
- A water flow stop button (5) on the QrX Handle (See 'c' below).
- Charging/mains power light (8) illuminates green when connected to mains power via the power adaptor.
- Power status light (9) illuminates when the Propulse NG Electronic Ear Irrigation System is turned on.

Note: The tricolour light merges from one colour to the next.

Green: *when there is adequate power from battery or mains.*

Amber: *battery power level is low and will need to be recharged soon.*

Red: *connect to mains via the power adaptor - battery needs recharging immediately.*

b) Water container/reservoir (1) is removable to facilitate filling and cleaning. Graduations are for indication only.

c) QrX Handle (3) and non-detachable hose. The QrX Handle accommodates the Propulse QrX Single Use Tips.
The QrX Handle incorporates a water flow stop button (5) which, when pressed and held firmly, stops the flow of water. The flow of water will resume upon release of the button, providing the footswitch is pressed.

d) The footswitch (12) - is connected to the main body via a jack plug/socket connection (10). The device will only function if the footswitch is connected.
The footswitch controls the flow of water - Depressing the footswitch starts the flow; releasing the footswitch stops the flow. The flow pressure can be adjusted by rotating the pressure / flow control knob (6) on the machine.

Please note: *Residual water in the handle and hose will continue to flow if the handle is not held in the vertical position or, if the handle is held in a position that is lower than the machine. To prevent residual flow, it is recommended that the QrX Handle be returned to its holder on the machine.*

TECHNICAL DATA

Performance:

Static pressure between:	0.27 bar (minimum setting) 3.45 bar (maximum setting)
Water jet pulses:	1200 per minute (approximately)
Maximum operating time:	10 minutes continuous use (with a recommended rest time of 2 hours)
Storage temperature range:	-5°C to 65°C
Storage relative humidity:	Up to 80%
Rechargeable battery:	6v Ni-MH 1300mAh
Power adaptor:	Input 100-240v ~ 50/60Hz Max 0.45A Output 9v DC 2A
Electrical Safety:	EN60601-1
EMC Compliance:	EN60601-1-2

GUIDE TO SYMBOLS

Class IIa Equipment

Type BF Electrical safety

Attention - Consult Accompanying Documents

IPX1 Protected against water droplets

Single use item

Conforms to the Medical Device Directive 93/42/EEC

Must be disposed of in accordance with European waste electrical and electronic equipment directive 2002/96/EC

OPERATING INSTRUCTIONS

These instructions are for general use. When required, refer to the detailed information in the second half of this manual.

- Ensure that **ONLY** suitably trained clinicians operate the device.
- Ensure that the warnings and cautions are observed.
- Ensure that the patient exhibits no contra indications.

- Ensure the unit has been cleaned prior to first use (refer to page 10 for detailed cleaning guidance).
- Mains electrical power is not necessary if the battery is adequately charged.
- The device may be operated whilst connected to the mains electrical supply using the Power Adaptor provided.
- Ensure that the footswitch is connected.
- The reservoir should be removed prior to filling.
- Fill the reservoir with a maximum of 700ml of warm water at 40°C. Monitor temperature regularly to ensure that patient comfort and safety is maintained. Refill as necessary.
- Fit a new Propulse QrX Single Use Tip to the QrX Handle.
- Set Pressure/Flow switch (6) to minimum (by turning anti-clockwise).
- Turn the Power Switch (7) to on (marked "I").
- With the footswitch depressed, check that the power status (9) is adequate (green indicator). If the power status is inadequate, (amber or red indicator), the Propulse NG Electronic Ear Irrigation System must be connected to the mains electrical supply using the Power Adaptor provided.
- Adjust the water pressure/flow to an appropriate value that is compatible with the treatment requirements and patient comfort.
- Direct the irrigator tip into the noots tank and switch on the machine for 10-20 seconds in order to circulate the water through the system and eliminate any trapped air or cold water. Ensure the water is warm before presentation to the patient.
- During treatment you can pause the flow by releasing the footswitch or firmly pressing and holding the water flow button (5) on the QrX Handle (3).
- After treatment empty the reservoir and operate the device to purge any residual water.
- Remove the Propulse QrX Tip and dispose of in accordance with local authority guidelines.
- Turn off Power Switch (7) after use and connect to the Power Adaptor to recharge the battery (if required).
- Clean the Propulse NG Electronic Ear Irrigation System unit every morning prior to use, with a cleaning tablet (See page 10).
- The Propulse NG Electronic Ear Irrigation System should only be transported in a Propulse approved carry case to prevent damage or contamination.
- If any changes in performance occur, turn off the Propulse NG Electronic Ear Irrigation System, disconnect from the mains electricity supply and **DO NOT** use. Please refer the machine to the Mirage Health Group Certified Service Centre (See page 11).

DETAILED INFORMATION

Fitting the Footswitch

The Propulse footswitch is connected to the main unit by a socket (10) in the side of the device. The Propulse NG Electronic Ear Irrigation System will **NOT** operate unless the footswitch is connected.

Filling the water container

It is recommended that:

i) The water container/reservoir (1) is removed from the device for filling and that the lid is always in place when the water container is in-situ on the device.

ii) The water reservoir must **NOT** be filled over the 700ml graduation mark to eliminate the risk of spillage. (The graduations on the reservoir are for indication only).

iii) Water above 40°C should **NOT** be used in order to avoid the risk of scalding and burns to the user and patient. Water below 40°C should **NOT** be used in order to avoid the risk of patient discomfort and dizziness.

Fitting the Propulse QrX Tip

The Propulse NG Electronic Ear Irrigation System is supplied with Ten Propulse QrX Single Use Tips. Use One Propulse QrX Tip per treatment.

To fit a Propulse QrX Tip

1) Remove tip from packaging – Tips are non-sterile.
2) Push Tip onto QrX Handle whilst retracting the QrX Locking Collar.
3) Release the QrX Locking Collar to secure tip to the QrX Handle.

To remove a Propulse QrX Tip,

1) Retract the QrX Locking Collar.
2) Grasp the used QrX Tip between forefinger and thumb. Pull gently from the QrX Handle.
3) Dispose of used tip in accordance with local authority guidelines. **DO NOT** reuse tips.

Propulse QrX Tips are available in boxes of 100, individually wrapped (non-sterile) tips from your normal Propulse supplier or from Mirage directly (UK only). Propulse QrX Tips are clearly branded with the Propulse logo on the tip and it's packaging. Only branded Propulse QrX Tips should be used with the Propulse NG Electronic Ear Irrigation System.

Replacing the Mushroom Valve

The Mushroom Valve is specifically designed to prevent water flowing out of the reservoir whilst filling. Should a replacement Mushroom Valve be required, please follow the steps below - This will help prevent possible damage to the water inlet valve.

1) Remove the reservoir from the Propulse NG.
2) Remove the old Mushroom Valve from the reservoir and discard.
3) Insert a new Mushroom Valve into the reservoir.
4) Return the reservoir to the machine.

Power Adaptor

The Power Adaptor can be used to charge the internal battery or to run the device from the mains electrical supply.

Connect the outlet lead of the Power Adaptor to the Power Adaptor socket (11) marked on the end of the product and to the mains electrical supply. Make sure the cord and Power Adaptor are positioned so that they will not be subjected to damage or stress or present a trip hazard.

Only use a Propulse branded Power Adaptor.

To reduce the risk of electric shock, unplug the unit from the power source before attempting to clean it externally.

The Power Adaptor must not be used outdoors or in damp areas.

The Propulse Power Adaptor will have been supplied with an appropriate electrical plug. If there are any problems connecting to the mains electrical supply consult a qualified electrician.

Battery Use And Care
We recommend that the battery be fully charged for 24 hours before you use the Propulse NG Electronic Ear Irrigation System for the first time.

For subsequent use the battery will normally require 16 hours to fully charge.

A new battery or one that has not been used for a long time may have reduced capacity the first few times it is used.

The battery is integral and is only replaceable by a Mirage authorised battery replacement centre. Refer to your Propulse supplier or the Mirage Health Group Certified Service Centre (UK customers only).

It is recommended that the battery is replaced after 400 charge cycles.

Environmental Protection

This symbol on the products and/or accompanying documents means that used electrical and electronic products should not be mixed with general waste. Please return to Mirage Health Group. Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

Disposing of used Propulse QrX Tips – Disposal should be in accordance with local authority guidelines and regulations for the disposal of clinical waste. Propulse QrX Tips should not be disposed of in municipal waste.

Transportation
Before the Propulse NG Electronic Ear Irrigation System is transported, the reservoir must be emptied and the machine should be operated until the handle and hose are empty of liquid. The reservoir should then be dried using a paper towel.

For safer transportation of Propulse NG Electronic Ear Irrigation System, Mirage recommends that the Propulse carry case is used to prevent damage or contamination.

Cleaning
Do not attempt to clean the Propulse QrX Tip. Use one Propulse QrX Tip per patient treatment and discard to clinical waste after use as this reduces the risk of cross infection between patients.

External cleaning of the Propulse NG Electronic Ear Irrigation System should be done by hand, wiping with a damp cloth only. Apply liquids to the cloth not the unit. Do not immerse the unit in water. Mild detergents and disinfectants may be used externally.

Internal cleaning of the Propulse NG Electronic Ear Irrigation System pumps and waterways.

The importance of using the correct strength cleaning solution cannot be overstated. A solution that is too strong will in time damage the Propulse NG Electronic Ear Irrigation System and one that is too weak will fail to provide the correct level of cleaning and decontamination. To this end Mirage Health Group provides a simple to use, effective, specific strength CHLOR-CLEAN® Propulse Cleaning tablet.

PRIOR to use:
1. Place one Propulse cleaning tablet into the reservoir, fill with warm water to the 500ml mark and wait for the tablet to completely dissolve.
2. Run the Propulse NG Electronic Ear Irrigation System for a few seconds to fill the pump and hose.
3. Leave to stand for 10 minutes.
4. Empty the reservoir of the solution, then fill the reservoir with cool boiled water or well run cold tap water and flush through the whole system to ensure no cleaning solution remains.
5. This cleaning procedure should be carried out prior to each day's usage of the ear irrigator.
6. **DO NOT** leave the solution in the unit for longer than stated.

Propulse cleaning tablets are available from your normal Propulse supplier or direct from Mirage (UK only). Please note: Damage caused to your Propulse NG Electronic Ear Irrigation System by not using the recommended cleaning agent will invalidate your warranty.

Other instruments used with Propulse NG Electronic Ear Irrigation System should be cleaned according to local guidelines.

Maintenance & Safety Inspections
To ensure optimum performance the Propulse NG Electronic Irrigation System should be serviced every 12 months. Service or repairs conducted by unauthorised agencies/organisations invalidate any or implied warranties from Mirage.

The Propulse NG Electronic Irrigation System should under-go routine electrical safety testing to ensure that it remains safe to use.

Users of the Propulse NG Electronic Irrigation System should carry out regular inspections to ensure that the handle and hose, power adaptor and cable, reservoir and main body of the machine are free from damage prior to use. If any damage is evident, the Propulse NG Electronic Irrigation System should NOT be used until replacement parts have been fitted. Only Propulse branded items should be used with the Propulse NG Electronic Irrigation System.

The Propulse NG Electronic Irrigation System is not user repairable and should be returned to your Propulse supplier or the Mirage Health Group Certified Service Centre (UK customers only) for service and/or repair:

MIRAGE HEALTH GROUP CERTIFIED SERVICE CENTRE
53 Purbeck Drive, Lostock, Bolton, Lancashire BL6 4JF
Tel: 0845 130 5445

The clinical procedures relating to the use of ear irrigators can be found on the following websites:
www.earcarecentre.com
www.entnursing.com/earcare.htm

Mirage is not responsible for the content or maintenance of third party internet sites.

Mirage can also advise on the availability of training courses offered by the relevant organisations.

Warranty
The Propulse NG Electronic Ear Irrigator carries a twelve months warranty (*subject to conditions) from the date of original purchase. Should any defect arise due to faulty material or workmanship, Mirage Health Group will provide a replacement unit upon receipt of the faulty Propulse NG, proof of purchase, information relating to the nature of the fault and details of where the item was purchased.

Should any of the "Accessory" items (listed below) prove to be faulty as a result of defective material or workmanship, Mirage Health Group will provide a replacement "Accessory" item free of charge upon receipt of the faulty accessory (*subject to conditions).

"Accessory" items are: Footswitch; Reservoir / Tank and Lid; Mushroom Valve and Washer; QrX Tip; Power Supply Lead and Power Transformer.

*Conditions of Warranty (applicable to Propulse NG and "Accessory" items).

The warranty does not cover:
- Accidental damage or damaged caused by misuse.
- Faults caused due to lack of maintenance.
- Damaged caused by using the Propulse NG for any use other than its intended use.
- Damage caused as a result of repair by any unauthorised agents – **ONLY** the Mirage Health Group Certified Service Centre should undertake repairs.
- Damage caused by the use of accessories / cleaning products that have not been recommended by Mirage Health Group.

This warranty is in addition to, and does not diminish your statutory or legal rights.

Additional user manuals and other accessories are available from Mirage Health Group Ltd at:
MIRAGE HEALTH GROUP Ltd
BioPark Hertfordshire, Broadwater Road, Welwyn Garden City, Hertfordshire. AL7 3AX UK
Tel: 0845 130 5440

Manufactured By
MIRAGE HEALTH GROUP Ltd
BioPark Hertfordshire, Broadwater Road, Welwyn Garden City, Hertfordshire. AL7 3AX UK
Tel: 0845 130 5440

EAR CARE TRAINING (UK only)
Mirage can advise on the availability of training courses offered by relevant organisations.

Mirage Health Group Ltd
BioPark Hertfordshire, Broadwater Road,
Welwyn Garden City, Hertfordshire.
AL7 3AX UK

Tel: 0845 130 5440 Fax: 0845 130 6440
Overseas Tel: +44 845 130 5440 Fax: +44 845 130 6440

www.miragehealthgroup.com

uksales@miragehealthgroup.com
internationalsales@miragehealthgroup.com

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